

REMARKS

The claimed invention

Newly introduced claim 53 recites a method of assembling a tissue engineered articular cartilage construct. The method includes transfecting a plurality of chondrocytes with a gene for IGF-I and seeding the transfected cells onto a biocompatible matrix comprising poly(glycolic acid). Claims 1-52 have been cancelled and replaced with new claims 53-63. No new matter is introduced by the new claims, which are supported by the specification as originally filed, especially the originally filed claims.

Claim Objections

Claim 10 is objected to. Applicant submits that this objection is moot in view of the cancellation of claim 10.

Rejections under 35 U.S.C. § 103

Claims 2, 4, 5-21, 43-45, 47, 48-50, and 52 stand rejected under 35 U.S.C. 103 as being obvious over Naughton in view of Breitbart. Applicant submits that newly presented claims 53-63 are patentable in view of Naughton and Breitbart, whether considered separately or together. Applicant submits herewith a declaration under 37 C.F.R. § 1.132 from Gordana Vunjak-Novakovic, Ph.D. In this declaration, Dr. Vunjak describes how difficult it is to maintain the phenotype of chondrocytes in culture. Manipulation of chondrocytes often causes them to de-differentiate to fibroblasts. Both transfection and seeding would ordinarily be expected to promote de-differentiation. However, the present inventors have discovered a method of both transfecting chondrocytes with a growth factor gene and seeding the transfected chondrocytes on a scaffold such that they produce collagen type II, the collagen variety found in articular cartilage. Applicant submits that this declaration demonstrates that the combination of Naughton and Breitbart fail to render obvious the subject matter of the invention because neither reference teaches how to prevent the de-differentiation of chondrocytes after either transfection or seeding, let alone both. Even if the mere suggestion of seeding transfected chondrocytes was sufficient, Applicant submits that one skilled in the art would have no expectation from either Naughton or Breitbart that the claimed invention could be successfully practiced. Rather, the skilled artisan would expect that the chondrocytes would fail to maintain their phenotype. As a result, applicant

submits that new claims 53-63 are patentable in view of Naughton and Breitbart, whether considered separately or together.

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Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Valarie B. Rosen", is written over a horizontal line.

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Date: September 15, 2004

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